**Appendix L: Scientific Review**

**Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Determining the scientific soundness of a study requires expert judgment about the degree to which the theoretical and methodological approach in a research design is appropriate to the topic and specific questions being investigated.

PI’s may choose from a wide variety of resources for such a review. Acceptable sources of scientific review may include, but are not limited to, peer review or local scientific review boards. “Peers” can include, but are not limited to, group leads or project leads knowledgeable about the proposed research approach, with no conflict of interest.

**Reviewer Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Reviewer Location/Command: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Reviewer Area of Expertise/Qualifications to Conduct Review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Relationship to PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The scientific review should consist of a review of the protocol, augmented by interactions with the principal investigator, as needed, for clarification.

1. Purpose(s): Is/are the objectives clearly stated?

2. Approach:

1. Does the approach follow a sound, scientific process (with recognition that processes

may differ based on the type of research being conducted)?

b. Are the conceptual framework, design, methods and planned analysis adequately developed, well integrated, and appropriate to the aims of the project and the nature of the data collection site(s)?

c. If applicable, are the kinds of results this design can produce appropriately matched with the scientific or programmatic claims the researchers hope to make?

d. Are the limitations of different aspects of the design clearly articulated?

e. Does the investigator acknowledge potential problem areas and consider alternative research approaches?

3. Investigator:

a. Are the Principal Investigator (PI) and Associate Investigators (the research team)

appropriately qualified to carry out this work and/or is ther an appropriate plan to train associate investigators?

b. If applicable, is the PI appropriately trained and well suited to supervise other investigators?

4. Recommendation:

\_\_\_\_\_ Recommend that the protocol is scientifically sound and that the IRB initiate its review.

\_\_\_\_ Recommend that the PI make the following changes to the protocol to satisfy the scientific review:

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Reviewer Signature Reviewer Printed Name